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FURTHER REMARKS

And regarding the rejection of claims 21, 22, 24, 28, 29, 40 and 41 under Sec. 102(b) over McLaughlin, US 5507818, claims 21 and 41 require a head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock. Again, such size limitations are material claim elements and must be taken into account. See, Marshall, 578 F.2d 301 [198 USPQ at 346]). McLaughlin does not describe either of these size limitations. The multipolar joint endoprosthesis of McLaughlin, in fact, is positively disclosed to be a hip or shoulder implant at column 1, lines 27-28, 32 and 51, and a hip in the detailed description and drawings, which joint implants are well known to be much larger than a basal thumb joint implant. The mention of the term, "etc.," in lines 28 and 32 does not describe the claimed limitations under the meaning of Sec. 102, and the Examiner is in error to suppose and state that any other joint is so described by McLaughlin. Moreover, the attachment of the component nearest the rear face of the ball is not acute; rather, it is perpendicular. And, the stem of the device of McLaughlin, i.e., distal component 13, which resides in the intramedullary canal of the femur, is straight, not inwardly curved. Thus, claims 21, 22, 24, 40 and 41 distinguish over McLaughlin under the meaning of Sec. 102. By virtue of their dependence, claims 28 and 29 also distinguish over McLaughlin.

Regarding the rejection of claims 21, 22, 24, 28, 29, 31, 32, 34-36 and 40-42 under 35 USC 102(e) over Townley, US 6096084, claims 21 and 41 require a head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock. Again, such size limitations are material claim elements and must be taken into account. See, Marshall, 578 F.2d 301 [198 USPQ at 346]). Townley '084 does not describe either of these size limitations. The modular ball and socket joint preferably with a ceramic ball of Townley '084, in fact, is disclosed preferably as a resurfacing hip implant in the abstract, last sentence; at column 1, lines 9-10; from column 1, line 18, to column 2, line 39; column 2, lines 43 and 45-50, and so forth; a hip or shoulder, preferably the hip, in the detailed description, e.g., column 4, line 19, et seq., and in drawings, which joint implants are well known to be much larger than a basal thumb joint implant. The general mention of other possible joints does not anticipate the claimed limitations under the meaning of Sec. 102. Moreover, the attachment of the component nearest the rear face of the ball is not acute; rather, it is perpendicular. Thus, claims 21, 22, 40 and 41 distinguish over Townley '084 under the meaning of Sec. 102(e). By virtue of their dependence, claims 24, 28, 29, 31, 32, 34-36 and 42 also distinguish over Townley '084. Also, Townley '084 is unavailable under 35 USC 103(c) since the inventive entity is the same as

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here, Dr. Townley, as the Examiner is well acquainted with, and both the invention of Townley '084 and the present invention were subject to assignment and have been assigned to the same owner, BioPro, Inc., as recorded in the Office on Reel 10155 Frames 892-894 and Reel 10116 Frames 869-870, respectively. See also, the Declaration with Exhibits submitted herewith.

Regarding the rejection of claim 42 under 35 USC 103(a) over Townley '065 in view of ASTM F 1377-98, Townley '065, which represents hip implant art, is not relevant art and thus not applicable under the meaning of Sec. 103(a). As verified and explained in parent application No. 09/352,472, a hip is a much larger joint than a basal thumb joint, the joint and implant have differing configurations, and they are in a far different sites of the anatomy; no person of ordinary skill in the art would look to hip art to improve pertinent basal thumb joint art. See, the Declaration with Exhibits submitted herewith. Only related art may be applied under Sec. 103(a). See, In re Sernaker, 702 F.2d 989 [217 USPQ 1, 5] (Fed. Cir. 1983); In re Oetiker, 977 F.2d 1443 [24 USPQ2d 1443, 1445-1446] (Fed. Cir. 1992). Furthermore, even if for the sake of argument Townley '065 could be applied with the ASTM, Townley '065, as explained above with respect to the Sec. 102(b) rejection employing it, does not describe the size and modularity features required by the base claim 40, nor is there any suggestion in it or in the ASTM to make a basal thumb joint implant, naturally a saddle joint, from the combination. Compare, the Declaration with Exhibits submitted herewith. In other words, Townley '065 does not suggest the invention of the base claim, the limitations of which are incorporated into claim 42, and the ASTM adds nothing to Townley '065 to make up for that deficiency in that regard. Moreover, the ASTM does not indicate how or where a porous coating would apply to a modular basal thumb joint implant.

Regarding the rejection of claims 21-27 and 37-41 under Sec. 103(a) over Wright Medical Technology in view of Townley '065, neither reference is applicable to a modular basal thumb joint implant. The Wright Medical implant is a one-piece basal thumb joint implant. The present claimed invention is a modular basal thumb joint implant. The Examiner has fully admitted at least two times of record that one-piece basal thumb joint implants and modular basal thumb joint implants are independent and patentably distinct species. See, the 05/25/01 Office action in the parent application, pages 2-3, from whence came the present divisional application; and, in the present application, the 10/12/2006 Office action, page 2, and the 01/17/2007 Office action, page 2. Thus, Wright Medical Technology is not related to the art of the present claims, and the Examiner has fully admitted it. Wright is not applicable under of Sec. 103(a). Townley '065, again which represents hip implant art, as explained above, is not relevant art and not applicable under the meaning of Sec. 103(a). Nor is the basal thumb joint implant of Wright related to the hip of Townley '065. Only references related to the art of the

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claimed invention and related to other references in combination can be applied under the meaning of Sec. 103(a). See, Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. Moreover, even if these two disparate references could be applied to the present claims, they would not suggest the invention claimed. Among other things, Wright Medical lacks a disclosure of modularity, a curved stem, a tri-flanged stem, an eccentric stem-to-head attachment site; plus, an eccentric head is not claimed hereby; rather, a generally hemispherical head is. Wright lacks disclosure of an acute stem-to-head attachment; it is perpendicular. Townley '065 lacks disclosure of modularity, size of the present claimed head and stem, generally acute site of attachment, and so forth. If the features of these two references were combined, a person of ordinary skill would be left in the dark as to which features should be present: should there be a large head? a small stem? a square stem? if the size of the implant were made small, should not a tri-flange or curved stem be jettisoned in favor of a stout, square, straight stem, as found in Wright, which has the small implant? Clearly, too, if combined, there would be no modularity, or, if it were deemed that Townley '065 shows stem-and-head modularity as in a large hip joint implant, if a device were made small, modularity of stem-to-head should be jettisoned as taught by Wright; there would be a perpendicular stem-to-head attachment, not acuteness as claimed hereby; there would be stem-to-head attachment at the center of the rear of the head, not in the eccentric manner claimed hereby. Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance, but even general guidance is not enough to establish a case of obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001); In re Hedges, 783 F.2d 1038 [228 USPQ 685, 687] (Fed. Cir. 1986). What is more, Dr. Leslie, a renowned hand surgeon, verified that he thought the one-piece basal thumb joint implant of Dr. Townley was a significant improvement over the implant of Wright; thus, if Wright were somehow considered relevant, it is rebutted by that. See, the Declaration with Exhibits submitted herewith.

Regarding the rejection of claims 21, 22, 24-26, 28, 29, 31, 32 and 34-37 under Sec. 103(a) over Wright Medical Technology in view of Abouaf et al., US 5871547, neither reference can apply to a modular basal thumb joint implant. The Wright Medical implant, again, a one-piece basal thumb joint implant, as explained above, is not relevant art and not applicable under the meaning of Sec. 103(a). Abouaf et al., which also represents hip implant art, as explained above with respect to Townley '065 or Townley '084, is not relevant art, and it is not applicable under the meaning of Sec. 103(a); nor is the simple, non-modular total knee joint implant of FIG. 4 of Abouaf et al. related to a basal thumb joint implant, much less the pertinent art of a modular basal thumb

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joint implant. Nor is the basal thumb joint implant of Wright related to the hip or knee of Abouaf et al. Only references related to the art of the claimed invention and related to other references in combination can be applied under the meaning of Sec. 103(a). See, Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. Moreover, even if these two disparate references could be applied to the present claims, they would not suggest the invention claimed. Among other things, Wright Medical lacks a disclosure of modularity, much less a Morse taper, an acute stem-to-head attachment, a curved stem, a tri-flanged stem, an eccentric stem-to-head attachment site. Again, an eccentric head is not claimed hereby; rather, a generally hemispherical head is. Abouaf et al. lacks disclosure of size of the present claimed head and stem, an acute stem-to-head attachment, a flanged stem, an eccentric stem-to-head attachment site, and so forth. If the features of these two references were combined, a person of ordinary skill would be left in the dark as to which features should be present: should the joint be a ball and socket joint? a ginglymous joint such as a knee? should there be condyles or a head? should there be a large articulating surface? should there be a stem or no stem? if a stem, a small stem, a large stem, a square stem, a nondescript, irregular stem? if the size of the implant were made small, should not a curved stem be jettisoned in favor of a stout, square, straight stem, as found in Wright, which has the small implant? Then, too, if combined, if a device were made small, modularity of stem-to-head should be jettisoned as taught by Wright and even perhaps no stem or no modularity by Abouaf et al. where the situs of the joint is located away from the hip, as well as no cup, trunnion nor Morse taper present; there would be a perpendicular stem-to-head attachment if a stem, not acuteness as claimed hereby; there would be stem-to-head attachment at the center of the rear of the head, not eccentric as claimed hereby. Would not the combined teachings of these references jettison different materials such as ceramic and metal for head and stem as the device gets smaller? At best, the artificial combination has ambiguous teachings, which are not even general guidance, but even general guidance is insufficient to establish a case of obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001); In re Hedges, 783 F.2d 1038 [228 USPQ 685, 687] (Fed. Cir. 1986).

Regarding the rejection of claims 27, 30 and 33 under Sec. 103(a) over Wright Medical Technology in view of Abouaf et al., in view of Townley '065, none of these references can apply to a modular basal thumb joint implant. The Wright Medical implant, again, a one-piece basal thumb joint implant, as explained above, is not relevant art. Abouaf et al., which also represents hip or knee implant art, as explained above, is not relevant art; nor is Townley '065, which represents hip implant art, which is not

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modular. Nor is the basal thumb joint implant of Wright related to the hip or knee of Abouaf et al., or the hip of Townley '065. Only references related to the art of the claimed invention and related to other references in combination can be applied under the meaning of Sec. 103(a). See, Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. Moreover, even if these three disparate references could be applied to the present claims, they would not suggest the invention claimed. Among other things, as noted above, in addition to its lack of modularity, much less a Morse taper, a curved stem, a tri-flanged stem, Wright Medical lacks a disclosure of an acute angle of attachment. Abouaf et al. lacks disclosure of size of the present claimed head and stem, an acute stem-to-head attachment, a flanged stem, and so forth. Townley '065 lacks disclosure of size of the present head and stem, of modularity, of a Morse taper, of an acute angle of attachment, and so forth. If the features of these three references were combined, a person of ordinary skill would be left in the dark as to which features should be present: should the joint be a ball and socket joint? a ginglymous joint such as a knee? should there be condyles or a head? should there be a large articulating surface? should there be a stem or no stem? if a stem, a small stem, a large stem, a nondescript, irregular stem, a tri-flanged stem? if the size of the implant were made small, should not a curved stem be jettisoned in favor of a stout, square, straight stem, as found in Wright, which has the small implant? Then, too, if combined, if a device were made small, modularity of stem-to-head should be jettisoned as taught by Wright and even perhaps no stem or no modularity by Abouaf et al. where the situs of the joint is located away from the hip, as well as no cup, trunnion nor Morse taper present; there would be a perpendicular stem-to-head attachment if a stem, not acuteness as claimed hereby. At best, this artificial combination, too, has ambiguous teachings, which are not even general guidance, but even general guidance is insufficient to establish a case of obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001); In re Hedges, 783 F.2d 1038 [228 USPQ 685, 687] (Fed. Cir. 1986).

The reasoning in the outstanding action is in serious error.

Please, therefore, withdraw the standing rejections.

The applicant, Charles O. Townley, passed away last year.

Respectfully submitted,

Dated: Apr. 17, 2007 A.D.

Encl

Christopher John Rudy, PTO #31873
209 HURON AVE, PORT HURON MI 48060
Telephone (810) 982-4221

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. THUMB-604DIV
For MODULAR BASAL THUMB JOINT IMPLANT

Declaration with Exhibits (37 CFR 1.132)

Attention: Group Art Unit 3738
Primary Examiner Brian E. Pellegrino

Commissioner for Patents, Alexandria, VA 22313-1450:

I, Christopher John Rudy, state and declare as follows:

I am the attorney of record (Reg. No. 31,873) in the present application and in parent Serial No. 09/352,472. I was attorney of record in the application that led to U.S. Pat. No. 6,096,084.

The inventive entity of the Townley '084 patent is the same as in the present application, Charles O. Townley. Both the invention of Townley '084 and the present invention were subject to assignment and have been assigned to the same owner, BioPro, Inc., with their assignments recorded in the Office on Reel 10155 Frames 892-894 and Reel 10116 Frames 869-870, respectively.

Attached hereto as Exhibits are copies of parts of declarations of record in the parent application, as follows:

Pages 1 (with postcard receipt) and 9-11 of the
DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS
of Patrick E. Pringle, filed on March 19, 2001.

Pages 1 (with postcard receipt), 3 and 4 of the
DECLARATION OF MARK S. LESLIE, M.D., filed
on May 22, 2000.

These verify among other things that hip implant art is not relevant to the art of basal thumb joint implants, and that the one-piece basal thumb joint implant of Dr. Townley was considered by Dr. Leslie to be clearly different from the Swanson titanium basal thumb joint of the Wright Medical Technology brochure, and that such is favorable for Dr. Townley's basal thumb implant.

All statements made herein of my own knowledge are true and on information and belief are believed to be true. Also, these statements were made with the knowledge that willful statements and the like so made are punishable by fine and/or imprisonment per 18 USC 1001 and such willful false statements may jeopardize the validity of this application or any patent issuing hereon.

Dated: April 17, 2007 A.D.

Christopher John Rudy

Decl. w/Exhibits (Exhibits)

Rec'd:

Amendment after Third Interview

15/CEP 3/9/2001
 • Supplemental Examination Report 3/9/2001
 • Declaration under 37 CFR 1.132 Traversing Rejections

15/CEP 3/9/2001
 Form PTO-1179 w/Official References

Re: Townley
 THUMB-393/440
 09/352,472.

Christopher John Rudy
 PTO #3182 3/9/2001

CRJ



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
 Patent Application No. 09/352,472
 Original Filing Date 07/14/99
 CPA Filing Date Aug. 17, 2000
 For BASAL THUMB JOINT IMPLANT

Attention: Group Art Unit 3738
 Examiner Brian E. Pellegrino
 Primary Examiner Bruce E. Snow

Commissioner of Patents
 Washington, D.C. 20231

DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS

I, Patrick E. Pringle, being warned that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent resulting hereon, state and declare as follows:

I am the undersigned, and am a citizen of the United States of America, and a resident of Smiths Creek, Michigan.

I am employed at BioPro, Inc., the assignor of the entire right, title and interest in the invention of the application of reference, being the current president of the corporation. I have worked at BioPro, Inc. for twelve years. Among my duties there, I assist in designing, evaluating and/or manufacturing prosthetic implants such as for the knee, elbow, hip, shoulder, big toe, and basal thumb joints. I am one of the co-inventors of U.S. patent No. 5,766,257 for an artificial joint having natural load transfer.

I understand that under 35 USC 103(a) claims of the present patent application stand rejected as being unpatentable over the applied references (which references I have reviewed, with copies thereof attached) as follows: 1) claims 1-8 over Kummer et al., U.S. patent No. 5,910,171; 2) claims 1-10, 12-14 and 16 over the "Townley Modular Shoulder" (BioPro brochure); 3) claims 17-20 over the BioPro brochure in view of the "Swanson Titanium Basal Thumb Implant" (Wright Medical Technology brochure); 4) claims 11 and 15 over the BioPro brochure in view of Bekki et al., U.S. patent No. 5,007,932. I believe that I have a sufficient understanding of the present invention, and formal drawings from the application, which pictorially illustrate principles and preferred embodiments of the invention, follow:

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I would respectfully disagree with the reasoning of the Examiner, and think that shoulder or hip joint art, and finger joint art, are not particularly related to basal thumb joint art.

Taking the shoulder joint as exemplary of what I understand that the Examiner considers to be more relevant from among the enarthrodial type joints of shoulder and hip, it first should be mentioned that I was shocked, saying, "No way!" when I heard that shoulder joint art, particularly a humeral implant, was being applied to a basal thumb joint. These joints are not related sufficiently to be interchangeable. (A hip, although not itself particularly relevant to basal thumb joint implant art either, perhaps would be more analogous.) Several considerations come to mind in support of this: size, configuration, and implant situs.

The size of a shoulder implant is vastly greater than that of a basal thumb implant. I fail to see how a person of ordinary skill in the art is given directions from the applied art to reduce the size of a large implant, intended for one part of the anatomy, a large part at that, to a smaller implant, intended for a different, small, remote part of the anatomy.

The configuration or shape of a humeral implant differs, and in some ways significantly, from a basal thumb joint implant as well. In general, for instance, humeral shoulder implants have more acute angles of attachments of their heads than do basal thumb joint implants. For example, the head to stem angle of the Townley Modular Shoulder is about fifty degrees whereas that of the Swanson Basal Thumb Joint appears to be nearly perpendicular. The angle of attachment of the basal thumb joint of the present invention preferably is about from sixty-five to seventy-five degrees, say, about seventy degrees. As well, typically, the heads of humeral shoulder implants span less than a hemisphere whereas those of basal thumb joints span more a hemisphere. The stems of humeral shoulder implants are, in general, relatively massive and not fluted to any pronounced degree. In contrast, the basal thumb joint implant stems are more slight, in general, and the basal thumb joint implant stem of the present invention preferably has a tri-flanged stem, for example, being T-shaped in cross-section. Moreover, a humeral shoulder implant often has a relatively large, solitary fin on the lateral side of the stem by the head for stabilization whereas no such solitary fin is found in basal thumb joint implants.

The situs of the implant differs significantly between the shoulder and the basal thumb. The humeral component of a shoulder implant has a stem designed for insertion into the upper reaches of a resected humerus, and has a head designed for mating with a glenoid socket cup or the glenoid socket itself. These parts of the anatomy differ significantly from the situs of the thumb. The shoulder is the most mobile joint in the body and is naturally an enarthrodial (ball and socket) type joint. The basal thumb, however, does not have naturally the mobility of the

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shoulder, and, in nature, is not a ball and socket type joint but rather is a saddle joint. It is only in artificial prosthetic implantation that the basal thumb joint is converted, as it were, to a ball and socket type connection. The long bone of the upper humerus is shaped differently, both internally and externally, from that of the metacarpus, into which the differing stems go.

Furthermore, I question why it is that a person of ordinary skill has not reduced the size of either a hip or a shoulder implant to develop a good basal thumb implant. And as I see it, for example, with respect to the Swanson Basal Thumb Implant, a person of ordinary skill did not "look to other prior art prostheses for designing the structure of the implant."

With respect to a finger digit implant such as that of Bekki et al., my initial impression when I was informed that finger digit joint art was being applied to a basal thumb joint was that of being confounded. These joints are not related sufficiently to be interchangeable. Several considerations come to mind in support of this: configuration, materials and implant situs.

The configuration of a finger digit joint implant differs fundamentally from that of a basal thumb joint implant. First, a typical finger digit joint implant as represented by Bekki et al. has a discontinuous head with respect to sphericity whereas the basal thumb joint under consideration has a head with an articulating surface that is uninterrupted as to its sphericity. This is so that the peculiarities of the finger joint such as a lesser degree of mobility or tendon interference are taken into account. The stem, too, of the Bekki et al. implant does not resemble that of the basal thumb joint implant of the present invention, in particular in its preferred embodiments, which can be readily seen.

The materials of the Bekki et al. joint, even as a composite structure, do not resemble those of the present basal thumb joint having a modular ceramic head. The Bekki et al. joint is said to be preferably either of ceramic or can have a metal-based, ceramic-coated head, with the implant component itself still of one piece. In contrast, the modular basal thumb joint implant of the present invention which has a ceramic head is a two-part component, and prefers a monolithic ceramic head part attachable to a monolithic metal stem part. Moreover, quick bone ingrowth is not relevant to the head of the modular ceramic-headed basal thumb joint implant of the invention. Such a consideration would be counterproductive to functionality of the thumb joint and harmful to the patient.

As to the implant situs, as alluded to above, a finger digit joint is significantly different from a basal thumb joint, both in natural and in artificial implant environments. The finger joint, for one thing, is significantly constrained whereas the basal thumb joint has far more degrees of freedom of movement,

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which is essential for a properly functioning joint.

It appears, therefore, that the application of the references noted above to the claims of the present invention is untenable.

All statements made herein of my own knowledge are true.
All statements made herein on information and belief are believed to be true.

Dated: March 9, 2001
Patrick E. Pringle

Attachments

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Decl. w/Exhibits (Exhibits)

Rec'd.

Amendment with Formal Drawings (9/11/99) (9/14/99) (9/14/99)

Record of Interview (1/10/00) (1/10/00) (1/10/00)

DECLARATION OF MARK S. LESLIE, M.D. (1/10/00)

#3900 (cl. #896)

Re: Townley

09/352,472

BASAL THUMB JOINT IMPLANT.

Christopher John Rudy
PTO #3873 5/16/2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of

Charles O. Townley
 Serial No. 09/352,472
 Filing Date 07/14/99
 For BASAL THUMB JOINT IMPLANT

To the attention of

Group Art Unit 3738
 Examiner Brian E. Pellegrino

Commissioner of Patents
 Washington, D.C. 20231

DECLARATION OF MARK S. LESLIE, M.D.

I, Mark S. Leslie, hereby state and declare that:

I am a citizen of the United States of America and resident of Traverse City, Michigan. Further, I am a licensed physician and orthopaedic surgeon practicing in Traverse City. I graduated with the M.D. degree in 1980 A.D., and have been certified by the American Board of Orthopaedic Surgeons since 1988. I specialize in surgery to the hand. Attached hereto is my Curriculum Vitae.

I understand that the claims of the present application have been rejected under Section 102(b), Title 35, United States Code, allegedly for a public use or sale of the invention prior to July 14, 1998. The Examiner stated in setting forth his rejection:

Claims 1-20 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. In May of 1998, Charles O. Townley sold the implant to Dr. Leslie. A product can be sold if its confidentiality is agreed/-implied upon. However, no such agreement for the confidentiality of the implant was agreed upon in the statement/explanation of the sale. The purchaser, Dr. Leslie, of the product/invention which was sold by the inventor/-company was asked, "Let me know how this works." However, BIOPRO/Dr. Townley did not receive any feedback from the buyer, so it was assumed that the thumb implant worked fine. Further purchases by the original buyer, Dr. Leslie, reinforced the fact that it was working well. This is not experimental use of the invention, since no agreement to keep it confidential was stated and no reports were required. Proper experimentation requires positive and/or negative feedback.

I also understand that prior to the rejection, Dr. Townley's attorney, Christopher John Rudy, had reported to the Examiner the following information, as he understood it, pertinent thereto:

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Leslie DECLARATION, page 3

I wish to note the following:

Although Mr. Rudy's report to the Patent Office as set forth on the previous page would seem to be accurate and reasonable in general, in correction of some of Mr. Rudy's understandings of the invention as would pertain to me as reported on the previous page, as I recall, with respect to his stating that the head was too large, only the head at the large end of the spectrum appeared to be a bit too large; the head at the small end of the spectrum seemed to be a bit too small. However, the intermediate sizes of the heads did not seem to present significant problems in my estimation. Also, as I recall now, I thought that the tri-flanges and curved stem and so forth could be acceptable, but, being part of a new and different thumb joint implant, should necessitate a trial. In addition, I did not purchase the basal thumb joints of the present invention which I implanted; these were actually purchased by Munson Medical Center Hospital, at which I have staff privileges.

Attached hereto are FIGS. 1-13 of the invention from the present application of Dr. Townley. I received, on a first user basis from BioPro, Inc., non-modular thumb joint implants such as depicted in FIGS. 1-3 and 12. The stems had cross-sections like those depicted in FIGS. 5 and 6. FIG. 12 most accurately depicts how the thumb joint implants I received looked, and FIG. 13 shows in general how the implant looks when implanted. I understand that the basal thumb joint implants which I received were made of a cobalt alloy. I did not receive any modular joint implants such as depicted in FIGS. 4 and 7-9, nor do I recall any porous coating on the implants I received such as depicted in FIGS. 10 and 11.

I did consider my use of the basal thumb joint implants experimental, especially for the first year, since they were clearly different from the otherwise broadly analogous Swanson titanium basal thumb joint known then, and thus, again, their configuration should require a clinical trial to determine if the new basal thumb joint implants could be adequately employed in general. Before the critical date of July 14, 1998, I received and implanted in a patient one non-modular basal thumb joint of the present invention as referenced above.

Although no formal written agreement of confidentiality was entered into between me and BioPro, Inc., I understood that the basal thumb joint implant invention, which was paid for by Munson Medical Center, was to be tried in confidence, and any such disclosure of the invention was on a need to know basis. Thus, I informed my patients in whom the joints were to be implanted that I would be implanting an experimental joint, and, of course, so as to attain informed consent, these patients viewed the joint. However, I made no public disclosure of the invention, nor did I promote it among my colleagues. Thus, the invention was kept in appropriate confidence, especially during the critical period.

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Also, although I understand that, based on the foregoing report from Mr. Rudy, he did not report to the Patent Office nor do I recall being expressly asked, "Let me know how this works," in contrast to that which the patent Examiner stated in setting forth his rejection, I understood that I was to keep track of results, but that reporting of results could be anecdotal. Thus, my reporting of results could be, and was done, informally. In general, I found that the joint performed fairly well, and I conveyed this at least on an informal basis to BioPro, Inc.

Accordingly, as I understand it, there was no public use by me nor non-experimentally-based sale of the present thumb joint invention before the critical date under 35 U.S.C. 102(b).

All statements made herein of my own knowledge are true, and all statements made herein on information and belief are believed to be true. Furthermore, these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.


Mark S. LeslieDate 5/10/07

Attmts: Attmt A (C.V.)
Attmt B (FIGS. 1-13)